

**EXHIBIT 2**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Shacknai, et al

Serial No. 10/022,482

Attorney Docket No.: 00-40175-US-P2

Art Unit: 1615

**COMPOSITIONS AND METHODS  
FOR HIGH SORPTION OF SKIN  
MATERIALS AND DELIVERY OF  
SULFUR**

**AFFIDAVIT UNDER 37 C.F.R. §1.132**

I, EUGENE H. GANS, hereby declare as follows:

I. Introduction

A. My Background

1. I received a Bachelor of Science (B.S.) in 1951 from Columbia University New York, New York; a Master of Science (M.S.) in 1953 from Columbia University New York, New York; a Doctor of Philosophy (Ph.D.) in 1956 from the University of Wisconsin Madison, Wisconsin.
2. Starting in 1956 and continuing to the present I have been involved in the development and testing of transdermal and targeted drug delivery systems. I am presently the Senior Medicis Advisor of Medicis Pharmaceutical Corp. and am involved in the development and licensing of cosmetic and drug delivery systems. For several years, I was a member of the AAPS/FDA/NIH/Academia/Industry Planning Committee to Establish Criteria for Assessing the Absorption of Active Agents & Drugs Into and Within the Skin.
3. I am an inventor of the invention described in United States Patent Application Serial No. 10/022,482 ("Application") and all of the earlier filed U.S. Patent Applications from which the Application claims priority.

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February 17, 2004 11:33 AM

*Eugene H. Gans*  
3/17/04

B. The Objective of the Testing of the Inventive System

1. The test described below was performed at my direction in order to show that the invention does not produce the malodor expected from a sulfur and sulfur derivative product in the prior art.
2. The test was designed to show a benefit of the present invention, which is a sulfur and sulfur derivative composition with no odor.

II. Experimental Procedure

A. The following test was performed under my direction. The following compositions were tested over the period of a month, during which the compositions were maintained at room temperature (25°C). Plexion SCT (an embodiment of the present invention) was used in the commercially packaged form. Sulfacet R and Sulfacet R Tint Free were prepared by mixing the "Sulfa-Pak" with the respective vehicles. All three compositions have 5% sulfur and 10% sodium sulfacetamide. Sulfacet-R Lotion has a flesh-tone tint.

1. Plexion SCT (an embodiment of the present invention) has the formulation set forth on Exhibit A attached hereto.
2. Sulfacet R Lotion has the formulation set forth on Exhibit B attached hereto.
3. Sulfacet R Tint-Free Lotion has the formulation set forth on Exhibit C attached hereto.

The test was a controlled odor evaluation conducted at 25°C on about equal amounts of each product spread on comparable, separate plates, which were at 25°C. The products were spread on the plates to form a film, in order to mirror a patient's application of each product to the skin. One evaluator sniffed each plate after a minute or so, and recorded the observed odors. The respective odors' degree and character were recorded as follows.

*[Handwritten signature]*  
3/17/04

## III. Experimental Data

Table 1

Time	Plexion SCT	Sulfacet R Lotion	Sulfacet R Tint Free
Initial	Fragrance odor	Very light sulfur	Very light sulfur
	No sulfur odor	Also chemical odor	Also chemical odor
1 day	Fragrance odor	Very light sulfur	Very light sulfur
	No sulfur odor	Also chemical odor	Also chemical odor
6 days	Fragrance odor	Very light sulfur	Very light sulfur
	No sulfur odor	Unpleasant odor	Unpleasant odor
13 days	Fragrance odor	Light sulfur odor	Light sulfur odor
	No sulfur odor	Chemical odor	Chemical odor
22 days	Fragrance odor	Light sulfur odor	Light sulfur odor
	No sulfur odor	Chemical odor	Chemical odor
35 days	Fragrance odor	Light sulfur odor	Light sulfur odor
	No sulfur odor	Chemical odor	Chemical odor



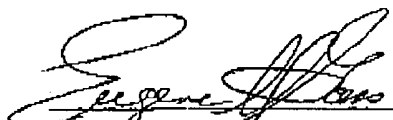
IV. Conclusions

I further declare and conclude from the fore-mentioned data the following:

- A. The present invention unexpectedly and surprisingly minimizes the malodors of sulfur and sulfur derivative compositions as compared to the prior art compositions.

I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application and any registration resulting therefrom.

Date: February 17, 2004

  
Dr. Eugene H. Gans